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CASE STUDY

FSP models for IVD Clinical Trials: Meeting Growing Pipeline Demands.

Conducting clinical trials can be both challenging and resource intensive. For mid-sized biotech companies, this can be especially true, as they often must balance limited resources with the need to launch new programs and manage a growing pipelines of products.

This was the challenge faced by a large genetic testing and diagnostics company, which needed a flexible solution to help with their expanding portfolio of clinical research projects across three product lines:

1. Women's Health
2. Organ Health
3. Oncology

The company initially struggled with insufficient resource allocation and time constraints, making it difficult to manage their teams effectively and launch new programs in a timely manner.

To overcome these challenges, they turned to a Functional Service Provider (FSP) model for their clinical trial needs. The FSP model involves outsourcing specific functions or services of clinical trial management to a third-party provider, rather than relying solely on internal resources.

In this case study, we will explore the genetic testing and diagnostics company's experience with the FSP model and the benefits it provided. **Specifically, we will examine how the FSP model allowed the company to streamline their clinical trial operations, reduce costs, and improve their overall efficiency.**

We will also explain the FSP model in more detail and highlight how it could be relevant to other mid-sized biotech companies facing similar challenges. By sharing this case study, we hope to provide insights and best practices for clinical operations that can help other companies navigate the complex world of healthcare research and development.

The Problem

The genetic testing and diagnostics company featured in this case study is a mid-sized organization with a diverse portfolio of products across Women's Health, Organ Health, and Oncology. As the company's clinical research program continued to grow, they faced a significant challenge in managing their expanding workload.

Specifically, they needed support for 18 studies across three functional areas:

- Study and Site Management
- Clinical Monitoring
- Data Management

To address this challenge, the sponsor sought a cost-efficient resourcing model that would allow them to balance their workload and optimize the utilization of their resources. They also needed a model that would provide transparency and a single point of contact to work directly with all internal study members.

The company's fluctuating workload made resource planning a particular challenge, as they needed assistance in ensuring a balanced workload across all studies. They recognized the importance of resource planning for successful clinical trial management and sought a solution that would allow them to scale their resources up or down as needed while maintaining quality and efficiency.

Ultimately, the company turned to an FSP model to meet their clinical trial management needs. By outsourcing specific functions and services of clinical operations to ProPharma, they were able to streamline their workload and improve efficiencies. The FSP model allowed the company to benefit from ProPharma's expertise while also maintaining transparency and control over their clinical research programs.

In the following sections, we will explore the sponsor's experience with the FSP model and how it helped the company to achieve their goals of cost efficiency, workload balance, and optimal resource utilization.

approach and solutions

An FSP team of 30 resources across eight different roles along with two Operations Managers was proposed to address the needs of the company's growing pipeline.

The goal of this 100% dedicated FSP team was to offer a flexible and adaptable solution that would allow resources to move across clinical programs during periods of high demand, and to provide a collaborative model with cross-functional support.

Under this model, ProPharma Clinical Operation Managers served as a single point of contact for issue escalation, resource allocation & management, and project management. This ensured adequate performance and deliverables while also streamlining communication and reducing administrative costs & burdens.

To facilitate effective communication and governance, a range of structures were implemented. This included regular status updates, weekly team meetings, monthly governance meetings, and quarterly business program reviews.

These structures helped to ensure that all stakeholders were aligned on project goals, timelines, and deliverables, and allowed for early identification and mitigation of risks.

To further enhance the effectiveness of the FSP model, built-in KPIs and a thoughtful risk mitigation process were put in place.

This allowed the sponsor company to focus on their core tasks while ProPharma managed non-core tasks and administrative activities. The KPIs and risk mitigation process also helped to ensure that the FSP team was delivering high-quality work and meeting key performance metrics.

key outcomes

The sponsor faced significant challenges managing their growing portfolio of clinical research projects across their Women's Health, Organ Health, and Oncology product lines.

With limited internal resources and insufficient resource allocation, they turned to an FSP model to provide flexible, cost-effective support for their clinical trial management needs.

The FSP team, consisting of over 30 resources across eight different roles and two Operations Managers, provided a collaborative model with cross-functional support and a single point of contact for issue escalation, resource allocation, and project management.

- ProPharma's FSP team delivered cost savings and increased efficiency while meeting or exceeding key study deliverables across multiple clinical programs.

Overall, the FSP model proved highly effective in helping the sponsor company to manage their clinical trial workload. By providing a flexible and adaptable resourcing solution, a collaborative model with cross-functional support, and robust governance and communication structures, the FSP team was able to meet the company's needs while also delivering cost savings and increased efficiency.

- Sponsor saved money by growing in headcount while alleviating HR costs and burden.
- FSP team executed timely monitoring visits across multiple studies, comprising over 7,250 patients/samples across 230 sites.
- The team executed around 100+ NDAs and developed and maintained timelines, DMP, EDC specification, and eCCG on time.
- Enrollment targets were met across several clinical programs, and database build activities and e-consents were developed and released to production on time.
- The team met database lock timelines and site activation projections on time across multiple clinical programs.
- The FSP model resulted in a 50% reduction in total queries and a 64% increase in evaluable subjects.

key considerations for implementing an FSP

Implementing an FSP model can be a smart choice for mid-sized biotech companies looking to manage their clinical trial operations more effectively.

However, there are several key considerations to keep in mind when implementing this type of model. Here are some insights and best practices to consider:

Identify the right partner

It is important to look for a partner who has a deep understanding of the industry, has experience managing clinical trials, and can offer flexible resourcing solutions that can be tailored to meet your specific needs.

Clearly define roles and responsibilities

Having a comprehensive grasp of roles and responsibilities is crucial for both the internal team and the FSP provider.

This entails establishing effective communication channels, aligning expectations, and defining performance metrics and key performance indicators (KPIs).

Ensure effective governance and oversight

Ensuring the success of the FSP model relies heavily on effective governance and oversight.

This involves implementing robust governance structures and processes, establishing transparent lines of communication, and delivering regular updates and feedback to both the internal team and the FSP provider.

Consider the impact on internal resources

Implementing an FSP model can significantly affect internal resources.

It is crucial to ensure that internal team members possess the requisite skills and expertise to collaborate effectively with the FSP provider. Moreover, providing them with adequate support to proficiently manage the model further contributes to its successful execution.

By fostering a collaborative approach between the internal team and the FSP provider, companies can maximize the potential benefits and achieve optimal outcomes.

Establish metrics for success

Properly measuring and evaluating the success of the FSP model is vital to its continued effectiveness. It is essential to establish comprehensive metrics for assessing success, encompassing factors such as cost savings, adherence to timelines, and the quality of outcomes.

By diligently tracking and analyzing these metrics, companies can gain valuable insights into the model's performance and identify specific areas for enhancement. Regular evaluation and continuous improvement efforts based on these metrics will ensure the FSP model remains optimized and aligned with organizational goals.

conclusion

This case study exemplifies ProPharma expertise, capabilities, and the unique value we brought to the sponsor's clinical trial management needs. By utilizing our FSP model, we successfully addressed their challenges of limited resources and a growing pipeline.

Our 100% dedicated FSP team, consisting of 30 resources across eight roles and two Operations Managers, delivered a flexible resourcing solution, optimizing resource allocation and workload balance. Through effective communication, governance structures, and established KPIs, we delivered high-quality work, exceeded performance metrics, and drove increased efficiency for the sponsor.

As the world's largest RCO, ProPharma continues to demonstrate our commitment to customer satisfaction, a customer-centric approach, and building long-standing relationships with our clients. This case study showcases our ability to offer tailored solutions that address the specific needs of mid-sized biotech companies, providing them with the expertise, resources, and support required for successful clinical trial management.